STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL
120 BROADWAY
SUITE 26C
NEW YORK, NEW YORK 10271

ERIC T. SCHNEIDERMAN
ATTORNEY GENERAL

ERIC J. STOCK
BUREAU CHIEF
Antitrust Bureau
Tel: 212-416-8282
Fax: 212-416-6015
Eric.Stock@ag.ny.gov

December 8, 2014

By Electronic Mail & Hand Delivery

Hon. Robert W. Sweet
United States District Judge
Daniel Patrick Moynihan
United States Courthouse
500 Pearl Street
New York, New York 10007-1312

Re: *New York v. Actavis*, 14-CV-7473 (RWS) – Recent Court Decision

Dear Judge Sweet:

I write to bring to the Court's attention a district court decision from last week that upheld antitrust claims by private plaintiffs challenging "hard switch" tactics engaged in by another brand name drug manufacturer, Reckitt Benckiser, Inc. ("Reckitt"). A copy of the decision in *In re Suboxone Antitrust Litigation* (MDL No. 2445) (E.D. Pa. Dec. 3, 2014), which denied Reckitt's motion to dismiss, is enclosed. Ironically, in the instant action, Defendants have pointed to Reckitt's actions with respect to Suboxone in an effort to suggest that "hard switch" tactics should not be viewed with suspicion. *See, e.g.*, Tr. 775:22-777:13, 813:2-814:17.

In *Suboxone*, the plaintiffs allege that in anticipation of imminent generic entry for the tablet version of its drug Suboxone, Reckitt sought to switch patients from the tablet to the "film" version of the drug, which has a patent that expires many years later. In furtherance of the switching effort, Reckitt announced in September 2012 that it intended to withdraw Suboxone tablets from the market, allegedly disparaged the tablet version of the drug, and actually removed the tablets from the market in March 2013, three weeks after generic entry. Generic versions of the tablet version of Suboxone cannot be automatically substituted at the pharmacy for prescriptions for the film version of the drug. Slip Op. at 2-4. The *Suboxone* plaintiffs allege that Reckitt's product switch was intended to thwart generic entry and unlawfully maintain its

monopoly position, in violation of section 2 of the Sherman Act.[1]

The court in *Suboxone* upheld several legal positions that New York has advocated before Your Honor in the instant action. For example, the court: (i) applied the test provided in *U.S. v. Microsoft* in determining whether Reckitt's withdrawal of its drug from the market could constitute exclusionary conduct (Slip Op. at 13); (ii) held that the standard for evaluating foreclosure was whether the most *cost-efficient* means of distribution is foreclosed, not whether *all* competition is foreclosed (Slip Op. at 21); and (iii) determined that harm to generic competition is an adequate basis for injunctive relief (Slip Op. at 69).

Reckitt also argued, like the Defendants in the instant action, that the new version of its drug (the film) was an improvement over the older version of the drug (the tablet), and that the introduction of a new product does not violate the antitrust laws. The *Suboxone* court agreed that the introduction of a new product does not in and of itself constitute exclusionary conduct, but explained that this was not the issue:

> [T]he key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit. This analysis must be undertaken with the somewhat unique characteristics of the pharmaceutical market in mind.

Slip Op. at 18. In upholding the antitrust claims, the court observed that Reckitt had allegedly engaged in "coercive measures" such as its announcement, six months before generic entry, that it would withdraw Suboxone tablets from the market. The court found that *"the threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film."* Slip Op. at 19 (emphasis added). The court also found that Reckitt's interference with patient and physician preferences supported liability, noting that patients who "preferred the tablets despite the safety concerns" might feel compelled to switch to the film due to the impending withdrawal. *Id.*; *see also id.* at 21 ("the withdrawal of Suboxone tablets is alleged to have . . . reduc[ed] consumer choice"). We further note that the *Suboxone* court found sufficient allegations of coercion even without the full withdrawal of the tablets prior to generic entry (Slip Op. at 9, 17-19), and without citing any impediments to access that rise to the level of those planned by Defendants in this case.

In closing arguments in this matter on November 24, we explained that there is an emerging pattern of case law indicating that while introducing and promoting a new product, standing alone, generally does not violate the antitrust laws, defendants cross over the line when they engage in manipulative, coercive conduct, such as placing impediments on patient access to prior versions of their drugs, as part of a "hard switch" tactic to foreclose generic competition. We submit that the *Suboxone* decision confirms and reinforces this trend, and is strong support for New York's antitrust claims in the instant action.

---

[1] For a summary of the conduct and anticompetitive effects at issue in *Suboxone*, see generally Slip Op. at 4-10. In other claims, the private plaintiffs also challenge Reckitt's alleged intentional delaying of regulatory processes (Slip Op. at 6-7) and its filing of a sham citizen's petition with the FDA (Slip Op. at 8).

Respectfully submitted,

Eric J. Stock

Cc (via email only):
Jack Pace III
Peter J. Carney
Martin Toto
Charles Moore